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TO: Commissioner for Patents
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In Re Application of : Christopher H. Porter		Examiner :	Ahmed, Aamer S.
		Art Unit :	3763
Serial No.:	10/821383		
Filed:	04/09/2004		

From: Arthur Freilich
Re: Attorney Docket: 203/505; MB-104 US

TOTAL PAGES TO FOLLOW: 15
DATE TRANSMITTED: 26 June 2007

MESSAGE

In response to the Notification of Non-Compliant Appeal Brief mailed 06/20/07, attached for filing is an amended appeal brief which corrects the issues cited in the Notification. More specifically, Section III (Status of Claims) has been revised to identify the claims involved in the appeal and the claims which have been cancelled. If any issues remain to be resolved, it is requested that Applicant's undersigned attorney be notified promptly.

Respectfully Submitted,

Arthur Freilich

AF/cg

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Porter, Christopher H.
Application No.: 10/821,383
Filed: 04/09/2004
For:
PERCUTANEOUSLY IMPLANTABLE MEDICAL DEVICE CONFIGURED TO PROMOTE TISSUE INGROWTH

Art Unit: 3763
Examiner: Ahmed, Aamer S.

I hereby certify that this correspondence is being transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at 571-273-8300.

6/26/07
Date

ARTHUR FREILICH
Name

Signature

APPEAL BRIEF

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal from the Office Action mailed on January 03, 2007, finally rejecting Claims 1, 3-9, 13-16 and 18-21. A Notice of Appeal was filed by fax transmission to the USPTO on March 16, 2007.

This Appeal Brief is submitted in compliance with MPEP section 1205. The fee required under 37 CFR § 41.20(b)(2) for filing an appeal brief should be charged to Deposit Account No. 501232.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is the assignee Medical Research Products-B, Inc., a California corporation.

II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1, 3-16 and 18-21 are pending in the application.

Claims 2 and 17 have been cancelled.

Claims 10-12 have been withdrawn from consideration.

Claims 1, 3-9, 13-16 and 18-21 which have been finally rejected are being appealed. Of these, only claims 1 and 16 are independent. Claims 3-9 and 13-15 depend directly or indirectly from claim 1. Claims 18-21 depend from claim 16.

IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to the Final Rejection (Office Action of January 03, 2007).

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention relates to an implantable medical device having a portion (i.e., "stud") configured to project percutaneously through a patient's skin. More specifically, the invention concerns a method and structure for creating an infection resistant barrier around the percutaneously projecting stud so as to avoid the prior art problems of infection, marsupialization, etc. discussed in the specification (e.g., page 5, lines 6-12 with reference to Figure 3). Briefly, the infection resistant barrier is formed by promoting soft tissue ingrowth into porous layers fixed to perpendicular (longitudinal and lateral) surfaces of the medical device housing. The provision of perpendicular porous layers having properties specifically selected to promote soft tissue growth into the interstices of both layers promotes vascularization, forms an infection resistant barrier, and provides improved device anchoring (e.g., page 2, lines 27-31).

Independent Claim 1

With reference to an exemplary embodiment shown in the Drawing (e.g., Figure 5), Claim 1 recites a medical device 42 having a stud 62 configured to project percutaneously through a patient's skin layers 50 (e.g., page 6, lines 24-31; Figure 8). The stud 62 has a longitudinal peripheral surface 66 and an outer end 64 (e.g., page 5, lines 24, 25; Figures 4,5). A first porous layer 70 is fixed to the longitudinal peripheral surface 66 (e.g., page 5, lines 30-33; Figures 4-6). The medical device 42 also has a lateral shoulder surface 60 located inwardly from the outer end 64 and the porous layer 70 (e.g., page 5, lines 20-25; Figures 4-6). The shoulder surface 60 carries a second porous layer 80 oriented substantially perpendicular to the longitudinally extending porous layer 70 (e.g., page 6, lines 14-20; Figure 5). The porous layers 70,80 are configured to promote soft tissue ingrowth (e.g., page 6, lines 3-4 and 24-28; Figure 8) as a consequence of having a pore size within the range of 50 to 200 microns and a porosity of between 60 to 95% (e.g., page 6, lines 3-6).

Independent Claim 16

With reference to an exemplary embodiment shown in the Drawing (e.g., Figure 5), Claim 16 recites a method of configuring an implantable medical device to have a portion adapted to project percutaneously, i.e., through a patient's skin. The claim recites providing a longitudinally projecting stud 62 having an outer end 64 and a peripheral surface 66 extending longitudinally inward from said outer end (e.g., page 5, lines 24,25; Figures 4,5). The claim also requires that a laterally projecting shoulder surface 50 be located inwardly from and oriented substantially perpendicular to the stud peripheral surface 66 (e.g., page 5, lines 20-25; Figures 4-6). The final recited step requires forming lateral and longitudinal porous layers respectively on said shoulder surface and said peripheral surface where each of the layers is restricted to having a pore size within a range of 50 to 200 microns and a porosity of between 60 to 95% for promoting soft tissue ingrowth and establishing an infection resistant barrier around the percutaneously projecting stud.

VI. GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL

1- Whether claim 1 is properly rejected under 35 U.S.C. 103(a) as "unpatentable over both Vito or Dahners et al in view of De Groot (EP 0367354)"; and

2- Whether claim 16 is properly rejected under 35 U.S.C 103(a) as "unpatentable over DeGroot in view of either Vito or Dahners et al".

VII. ARGUMENT

The claimed invention pertains to an implantable medical device having a stud portion configured to project percutaneously through an incision in a patient's skin. In an exemplary application of the invention, the medical device comprises a hearing aid (Figure 1) having a distal end, or stud, which projects percutaneously into the patient's ear canal (e.g., page 4, line 22 to page 5, line2). As stressed in the Specification (e.g., page 5, lines 6-12, Figure 3), the conventional use of such implanted devices has been problematic because of the tendency of soft tissue to grow downwardly at the percutaneous penetration site resulting in the formation of sinus tracts susceptible for infection. As explained on Specification page 5, "Continued downgrowth can lead to marsupialization and ultimately can result in expulsion of the implant". To mitigate these problems, embodiments of the invention are configured to promote soft tissue growth into the interstices of perpendicular porous layers to avoid the formation of sinus tracts and create an infection resistant barrier around the percutaneous penetration site (e.g., page 5, lines 13-19). More particularly, embodiments of the invention employ perpendicular porous layers respectively fixed to longitudinal and lateral surfaces of the implanted device which have a pore size of 50 to 200 microns with a porosity of between 60 to 95%. (e.g., page 6, lines 1-6). By mitigating the aforementioned problems traditionally encountered with percutaneous implants, a variety of potential medical applications may now be realizable.

All of the claims were finally rejected on some combination of Vito, Dahners and DeGroot.

Vito (US 5,131,838)

Vito describes an orthopedic device intended to prevent screws from loosening and migrating out of a patient's bone. More particularly, Vito teaches a fixation assembly for orthopedic applications comprised of a screw 10 having a shank portion 40, a recessed middle section 35, and a lower threaded section 45. A locking ring 30 surrounds the recessed middle section. The screw and locking ring combination is used to attach an orthopedic plate 20 to a bone 50.

The Vito device is intended for subcutaneous use to reliably attach a plate to a bone. Nothing in Vito suggests that any part of his fixation assembly is configured to project percutaneously through a patient's skin. Thus, Vito would not encounter the problems of soft tissue downgrowth, sinus tract formation, and marsupialization addressed by Applicant.

The Final Rejection of 01/03/07 erroneously suggests that Vito discloses a "longitudinal porous layer thereon for promoting soft tissue ingrowth", citing col. 3, line 9. But this cited portion only relates to "bone growth" which is quite distinct from soft tissue ingrowth.

The Final Rejection further errs in asserting that Vito shows a "shoulder surface (area between 45 and 35)" which "has a lateral porous layer thereon...for promoting soft tissue ingrowth". The sole purpose for the Vito recessed area 35 is to accommodate elastic locking ring 30. There is no suggestion in Vito that soft tissue, or even bone, is intended to grow into recessed area 35. Rather, it is intended that the ring 30 be "free to move" in recessed area 35 but not beyond the shoulders of the recessed area (col. 3, lines 26-30). More particularly, note col. 4, lines 1-7 which further explains the function of the Vito fixation assembly which is to lock the orthopedic plate 20 in place and yet allow "free screw rotation"..."should additional tightening be needed to more firmly secure the plate to the bone". In view of this crucial aspect of Vito, it would be inconsistent for Vito to suggest promoting soft tissue ingrowth onto the shoulder surface of his recessed area 35. Indeed Vito teaches away from any such suggestion or teaching because any significant tissue ingrowth onto the shoulder surface of recessed area 45 would diminish his ability to allow "additional tightening".

Dahners (US 6,99,677)

The Dahners reference is similar to Vito in that it too describes an orthopedic device for fixing a plate 60 to a bone 13. More particularly, Dahners describes a particularly configured fastener, or screw, 10 and a fastener receiving plate 60. The plate 60 has apertures A1, A2 which allow for multi-angular insertion of the fastener into the apertures to better fixate the plate 60 to the bone. As with Vito, nothing in Dahners suggests that any part of his fastener 10 is intended to project percutaneously through a patient's skin layers. Nor is Dahners concerned with anchoring or preventing infections in soft tissue. Accordingly, the Dahners device would not encounter the problems of soft tissue downgrowth, sinus tract formation, and marsupialization addressed by Applicants.

The Dahners fastener 10 comprises a specially configured screw (Figure 1) including an elongate section 20 having an outer surface 25 carrying an external thread 31. The fastener 10 further includes a head section 40 having an outer surface 45 carrying an external thread 51.

The Final Rejection asserts that the elongate section 20 comprises a longitudinal peripheral surface having a "longitudinal porous layer thereon for promoting soft tissue ingrowth", citing col. 2, line 60. With due respect, it is pointed out that the cited portion of Dahners lacks any mention of promoting soft tissue ingrowth. Rather, the cited portion explains that the "tappable contact region" comprises a "porous fiber metal matrix". The "tappable contact region" refers to an inside surface of the "fastening receiving member" 60 and not to the fastener 10. The porous matrix is apparently for the purpose of assisting the threading of the fastener 10 into the receiving member 60 at various angles.

The Final Rejection also errs in asserting that "shoulder surface (45)" has a "lateral porous layer thereon... for promoting soft tissue ingrowth. The cited portion of Dahners (i.e., col. 2, line 60) fails to even remotely support this assertion.

DeGroot (EP 0367354)

DeGroot describes a percutaneous implant comprised of a subcutaneous part 1 and a percutaneous part 10. The subcutaneous part 1 comprises a mesh sheet 2 which functions to promote tissue ingrowth. Note in DeGroot's Figure 2 that the mesh sheet 2

is implanted substantially parallel to the patient's skin 20. The mesh sheet 2 carries a holding member 3 which includes a round hole having an internal screw thread 4. The percutaneous part 10 comprises a tubular structure having an external screw thread 14 configured to mate with the holding member internal screw thread 4. A hollow tube 30 for transferring fluids extends through the bore of the tubular structure 10.

As noted in DeGroot col. 5, line 4, "during the healing process, the skin 20 will adhere to the percutaneous part 10" (i.e., the longitudinal surface of the tubular structure 10) "in a manner comparable to the manner in which gums adhere to a tooth". Thus, DeGroot fails to suggest the use of a porous layer on the longitudinally extending surface of the percutaneous tubular structure for promoting tissue ingrowth. Rather, DeGroot's teaching of using a mesh sheet is limited to subcutaneously implanting the sheet substantially parallel to the user's skin. Accordingly, DeGroot fails to suggest Applicants' teaching of providing porous layers extending both longitudinally and laterally adjacent a percutaneously projecting stud for enabling tissue ingrowth along perpendicular surfaces to enhance bacteria resistance and device anchoring.

Claim 1

In the Office Action of 01/03/07, independent claim 1 was rejected under 35 U.S.C. 103(a) as unpatentable over both Vito or Dahners in view of DeGroot. The Office Action asserts that Vito and Dahners each disclose the device as described in claim 1 except for the pore size of the porous layer and that DeGroot discloses a porous layer having a pore size and porosity as claimed. The Office Action then concludes "It would have been obvious...to modify the device or (sic) Vito or Dahners by adding the pore size...taught by DeGroot".

In reply, as detailed above, it is courteously urged that the Examiner has erred in his interpretation of the Vito and Dahners teachings. In fact, neither suggests a medical device having a stud carrying perpendicular longitudinal and lateral porous layers for projecting percutaneously for promoting soft tissue ingrowth.

And, in any event, why would it be obvious to modify Vito or Dahners in view of DeGroot? Would it serve any useful purpose? If so, what? Applicants' assert that it would not be obvious to modify Vito or Dahners in view of DeGroot because to do so would surely compromise their performance of the disclosed devices. That is the substitution of the DeGroot porous layer into the Vito or Dahners devices would surely compromise their essential function of securely and reliably fastening a plate to a bone.

Claim 16

The Office Action finally rejects independent method claim 16 under 35 U.S.C. as unpatentable over DeGroot in view of Vito or Dahners. The Action asserts that DeGroot discloses a method of configuring an implantable medical device with a portion adapted to project percutaneously including the step of providing a porous layer having a pore size within a range of 50 to 200 microns and a porosity of between 60 to 95%. The Action apparently recognizes that DeGroot fails to disclose the steps of providing a longitudinal peripheral surface and a lateral shoulder surface and forming a longitudinal porous layer on the peripheral surface and a lateral porous layer on the shoulder surface. But the Examiner concludes "It would have been obvious...to modify...DeGroot by incorporating the steps of providing longitudinal and peripheral surfaces...as taught by either Vito or Dahners...".

Again, Applicants' must dispute that it would be obvious to make the proposed combination. Where is the motivation? In what way would the DeGroot device be enhanced by incorporating any features of Vito or Dahners? Moreover, it has been stressed herein that the Examiner has erred in interpreting the Vito and Dahners references and, in fact, neither suggests providing perpendicular porous layers for promoting soft tissue ingrowth and establishing an infection resistant barrier.

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Conclusion

In view of the foregoing, it is respectfully asserted that claims 1, 3-9, 13-16 and 18-21 patentably distinguish the invention over the art of record.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. A medical device comprising:

a stud configured to project percutaneously outward through a patient's skin layers;

said stud defining an outer end and having a longitudinal peripheral surface extending inwardly from said outer end;

said peripheral surface having a longitudinal porous layer thereon for promoting soft tissue ingrowth;

a shoulder surface oriented substantially perpendicular to said stud peripheral surface and located inwardly from said stud outer end and from said longitudinal porous layer; and wherein

said shoulder surface has a lateral porous layer thereon oriented substantially perpendicular to said longitudinal porous layer for promoting soft tissue ingrowth; and wherein

at least one of said porous layers is characterized by a pore size within the range of 50 to 200 microns with a porosity of between 60 to 95%.

3. The medical device of claim 1 wherein at least one of said porous layers comprises a mesh of fibers.

4. The medical device of claim 1 wherein at least one of said porous layers comprises a mass of sintered material.

5. The medical device of claim 3 wherein said fibers are of metal material from within a group comprised of titanium, nitinol, silver, and stainless steel.

6. The medical device of claim 3 wherein said fibers are of polymeric material.

7. The medical device of claim 4 wherein said mass is formed of metal material from within a group comprised of titanium, nitinol, silver, and stainless steel.

8. The medical device of claim 4 wherein said mass is formed of polymeric material.

9. The medical device of claim 1 wherein said stud carries means for promoting healing.

13. The medical device of claim 1 further including a transitional layer mounted on said stud between said stud outer end and said longitudinal layer.

14. The medical device of claim 1 further including a cap configured for mounting on said stud outer end.

15. The medical device of claim 1 wherein said porous layers are formed of biocompatible material.

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16. A method of configuring an implantable medical device with a portion adapted to project percutaneously comprising the steps of:

providing a longitudinally projecting stud on said device having an outer end and a peripheral surface extending longitudinally inward from said outer end;

providing a laterally projecting shoulder surface on said device located inwardly from and oriented substantially perpendicular to said stud peripheral surface; and

forming a lateral porous layer on said shoulder surface and a longitudinal porous layer on said peripheral surface wherein said porous layers each have a pore size within a range of 50 to 200 microns and a porosity of between 60 to 95% for promoting soft tissue ingrowth and establishing an infection resistant barrier.

18. The method of claim 16 wherein said step of forming a porous layer comprises forming at least a portion of said layer with a mass of sintered material.

19. The method of claim 16 wherein said porous layer is formed at least in part of metal material from within a group comprised of titanium, nitinol, silver, and stainless steel.

20. The method of claim 16 wherein said porous layer is formed at least in part of polymeric material.

21. The method of claim 16 wherein said porous layer is formed at least in part of polymeric material.

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IX EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None